

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
SPRINGFIELD DIVISION

U.S. DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BLACKSTONE MEDICAL, INC.,

Plaintiff,

v.

OSIRIS THERAPEUTICS, INC.,

Defendant.

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Cause No. _____

ORIGINAL COMPLAINT

Blackstone Medical, Inc. (“Blackstone”), Plaintiff, files this Original Complaint against Osiris Therapeutics, Inc. (“Osiris”), Defendant, as follows:

I. Nature of the Lawsuit

1. Blackstone asks the Court to immediately enjoin Osiris, pending the outcome of arbitration, from closing upon, or otherwise carrying out, Osiris’s agreement to sell its Osteocel business to NuVasive, Inc. (“NuVasive”). While Osiris has until September 8, 2008, to close without triggering a default, Osiris has told Blackstone that they intend to close the transaction as soon as possible following a shareholder meeting scheduled to take place tomorrow, July 24, 2008, at 2:00 p.m. EDT.

2. Blackstone has an exclusive, long-term distribution agreement (the “Distribution Agreement”) with Osiris under which Blackstone is entitled to purchase 80% of Osiris’s production of Osteocel and to be the exclusive spinal implant manufacturer selling Osteocel in the United States. Osiris and Blackstone agreed to first negotiate, and then submit to binding arbitration, all controversies or claims arising out of, or relating to, the Distribution Agreement. If Osiris is permitted to close on its agreement to sell Osteocel to NuVasive, a competing spinal

implant manufacturer, the competitive landscape will be irrevocably altered and the arbitrator of Blackstone's claims will be unable to award complete and effective relief in injunctive, declaratory, or monetary form.

3. Money damages will be inadequate, and difficult or impossible to accurately assess, because of the inherent uncertainty of determining what profits Blackstone would have enjoyed from its total portfolio of spine products but for the loss of its Osteocel supply and market exclusivity. The Osiris transaction also threatens irreparable harm to Blackstone through the risk of disclosure of Blackstone's confidential information. The parties agreed that injunctive relief would be appropriate to prevent threatened wrongful disclosures of confidential information.

II. Jurisdiction and Venue

4. This Court has personal jurisdiction of this lawsuit under 28 U.S.C. § 1332(a). The matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between a citizen of the State of Massachusetts and a citizen of the State of Maryland.

5. Venue is proper in this Court under 28 U.S.C. § 1391(a) because a substantial part of the events giving rise to Blackstone's claims occurred in this judicial district.

III. Parties

6. Blackstone is a corporation organized and existing under the laws of Massachusetts, and its Massachusetts facility is located at 90 Brookdale Drive, Springfield, Massachusetts 01104.

7. Osiris is a corporation organized and existing under the laws of Delaware, and its principal place of business is located at 7015 Albert Einstein Drive, Columbia, Maryland 21046-

1707. Osiris may be served with process through its registered agent, The Corporation Trust Incorporated, located at 300 E. Lombard Street, Baltimore, Maryland 21202.

IV. Factual Background

8. Blackstone's Original Complaint, Motion for Temporary Restraining Order and Preliminary Injunction, and Memorandum in Support of Motion for Temporary Restraining Order and Preliminary Injunction, filed concurrently herewith, are supported by the declarations of Alan Milinazzo, Michael Finegan, Tom Brewer, and Brent Alldredge. These declarations are incorporated herein by reference.

V. Factual Background

9. Blackstone, a wholly owned subsidiary of Orthofix International N.V. ("Orthofix"), manufactures and distributes high-value, minimally invasive products used by surgeons in spinal fusion and other spine surgeries. The products Blackstone manufactures and/or distributes fall into two categories: "metal," consisting of the screws, plates, and associated instruments used to join or secure spinal bone; and "biologics," consisting of synthetic and human stem cell-based bone substitutes used to repair and promote growth of spinal bone. Blackstone's entire suite of metal and biologics products is offered to surgeons through Blackstone's network of independent distributors and direct-sales employees.

10. A valuable part of Blackstone's biologics portfolio is Trinity™, which is a viable alternative to autograft (transplantation of cancellous bone from another part of the patient's own body), particularly for patients less able to endure the added trauma of bone harvesting. Trinity™ is an integral part of Blackstone's suite of metal and biologics products, and complements sales and uses of Blackstone's other metal and biologics products.

11. Blackstone introduced Trinity™ to the U.S. market in 2006 after entering into the Distribution Agreement with Osiris, dated November 10, 2005. Osiris manufactures and is believed to own the intellectual property rights to Osteocel, the product Blackstone brands and sells as Trinity™. Osiris manufactures and labels Trinity™ to Blackstone's order. Among others, the Distribution Agreement provides Blackstone with the following valuable rights:

- (a) the right to purchase 80% of Osiris's production of Osteocel packaged for resale as Trinity™;
- (b) the right to be the exclusive spinal implant manufacturer distributing Osteocel in the United States for the duration of the Distribution Agreement, provided Blackstone continues to commit to purchase 80% of Osiris's production of Osteocel; and
- (c) the right to renew the Distribution Agreement for successive one-year renewal terms following the expiration of the initial term on December 31, 2008.

While the Distribution Agreement is assignable under limited circumstances, it also provides: "Osiris agrees that it shall not enter into any agreement with or grant any rights to a Third Party that would conflict with or violate the terms of this Agreement."

12. The Distribution Agreement also prohibits Osiris from disclosing Blackstone's confidential information to third parties or using that information for any purpose other than to perform Osiris's obligations under the Agreement. Confidential information as defined by the Distribution Agreement includes "sales information, customer and potential customer lists and identities, product sales plans," and other information about the market for Trinity™ that Blackstone has created. Because of the critical importance of their confidential information,

Blackstone and Osiris acknowledged and agreed that damages for the breach or threatened breach of this agreement may be inadequate and that either party is entitled to seek temporary or permanent injunctive relief in order to protect their confidential information.

13. Blackstone and Osiris negotiated and memorialized in the Distribution Agreement a specific dispute resolution procedure embracing good-faith, high-level negotiation of disagreements followed by arbitration. If good-faith negotiations of the parties' representatives fail to result in resolution of a controversy or claim, the controversy or claim is escalated to the respective presidents of Osiris and Blackstone, who are obliged to negotiate towards a resolution for at least thirty days. It is only after this cooling-off period for negotiations that either party may proceed to seek arbitration of the controversy or claim.

14. The Distribution Agreement obliges Osiris and Blackstone to submit unresolved controversies or claims to binding arbitration before the American Arbitration Association ("AAA") under the AAA's Commercial Arbitration Rules. In addition, the parties agreed to endeavor to jointly appoint as sole, disinterested arbitrator "an attorney knowledgeable in stem cell products and experienced in handling commercial disputes." It is only if the parties are unable to jointly select an arbitrator within thirty days after initiation of proceedings that the AAA will appoint an arbitrator under its Commercial Rules. If Blackstone's claims cannot be resolved through continued negotiations with Osiris, Blackstone intends to initiate arbitration proceedings pursuant to the dispute resolution procedures of the Distribution Agreement.

15. It is not an overstatement to say that Blackstone, through its investment in testing, marketing, and selling Trinity™, made Osteocel a valuable commodity and Osiris a successful, revenue-generating company. When Blackstone and Osiris executed the Distribution Agreement, there was no existing market for Osteocel. Osiris, for this reason, required Blackstone to

implement a market-launch strategy and to agree to use its best efforts to advertise and distribute Osteocel. Blackstone has made a significant investment in advertising and marketing, in purchasing commercial freezers and other equipment, dry-ice products, and special delivery mechanisms, as well as in training personnel to properly handle Osteocel. Because of Blackstone's significant investment of time and resources in developing a market for Trinity™, Blackstone has grown U.S. sales of Trinity™ from nothing in 2005 to \$13,324,370 in 2007 and an estimated \$18-20 million for full year 2008. In 2006 and 2007 Blackstone's purchases of Trinity™ from Osiris constituted the majority of Osiris's revenue.

16. On May 8, 2008, Osiris publicly announced that it had agreed to sell the Osteocel product line to NuVasive for up to \$85,000,000. NuVasive is a direct competitor of Blackstone's in the market for metal products used in spine surgery. Immediately after the public announcement, Alexis Lukianov, NuVasive's Chairman and CEO, contacted Alan Milinazzo, Orthofix's President and CEO and Blackstone's CEO, concerning the transition of the distribution of Osteocel from Blackstone to NuVasive. In a telephone conversation with Mr. Lukianov on June 8, 2008, an e-mail from Mr. Lukianov dated June 8, 2008, and a personal meeting with Mr. Lukianov and Jason Hannon, NuVasive's Senior Vice President and General Counsel, on June 13, 2008, NuVasive confirmed to Mr. Milinazzo that it intends to begin selling Osteocel in the United States as early in 2008 as possible.

17. By letter dated July 7, 2008, Osiris informed Blackstone that any effort to renew the Agreement for 2009 and beyond will not be honored by Osiris or NuVasive. Mr. Milinazzo, after reading this letter, contacted Randall Mills, Osiris's CEO, and met with him on July 17, 2008 and spoke with him by telephone on July 21, 2008. In both discussions, Mr. Mills said he did not know whether NuVasive would begin selling Osteocel in the United States in 2008,

notwithstanding NuVasive's stated intention to do so. Mr. Mills confirmed Osiris's intention to close the sale of its Osteocel business to NuVasive as soon as possible after receiving Osiris shareholder approval on July 24, 2008.

18. By letter dated July 11, 2008, Blackstone responded to Osiris's July 7, 2008 letter and notified Osiris that the proposed NuVasive transaction constituted a "controversy or claim" within the meaning of the dispute resolution provisions of the Distribution Agreement. In this letter, Blackstone also demanded that discussions between Blackstone's and Osiris's CEOs take place in accordance with the Distribution Agreement's dispute resolution provisions. With the exception of the limited discussions described above, Osiris's CEO has not engaged in meaningful negotiations to address Blackstone's claims. Mr. Mills has taken the position that Blackstone should address its claims with NuVasive, as Osiris's successor, after the closing. Moreover, Mr. Mills has stated that he would be unwilling to postpone the closing of Osiris's sale of Osteocel to NuVasive to allow for the full thirty days' CEO-to-CEO negotiations or subsequent arbitration required by the Distribution Agreement. Negotiating or arbitrating with NuVasive is unacceptable to Blackstone because NuVasive is a direct competitor of Blackstone's and cannot, as a practical matter, fulfill Osiris's obligations to Blackstone under the Distribution Agreement.

19. Despite what Osiris and NuVasive have told Blackstone privately, they have publicly stated that they intend to honor the Distribution Agreement. During Osiris's first quarter 2008 earnings conference call, for example, Randall Mills, Osiris's President and CEO, said: "But I will say that we intend to and NuVasive intends to operate under the Orthofix agreement as stipulated for the remainder of 2008." And in an article from the investor relations section of NuVasive's website, NuVasive states: "The Company expects to honor the current

2008 distribution agreements held by Osiris.” But such statements are belied by the very structure of the Asset Purchase Agreement (the “APA”) between Osiris and NuVasive, which is scheduled to close as early as July 24, 2008, immediately following Osiris’s shareholder meeting at which Osiris’s shareholders are expected to overwhelmingly approve the sale of Osteocel to NuVasive. According to Osiris’s Definitive Proxy Statement, which was publicly filed with the U.S. Securities and Exchange Commission (the “SEC”) on July 3, 2008, 47% of Osiris shares already are committed through voting agreements to approve the Osteocel sale.

20. Osiris’s proposed sale of the Osteocel product line to NuVasive necessarily and anticipatorily breaches the Distribution Agreement in at least the following ways: First, the APA requires Osteocel to supply, and NuVasive to purchase, at least 250,000 cubic centimeters (“ccs”) of Osteocel in the eighteen months following closing on the APA. Osiris has publicly projected that one-third of the \$52,000,000 in revenue from these sales will be received during the remainder of 2008. NuVasive officials have stated that they intend to begin selling Osteocel in the United States as early in 2008 as possible. NuVasive is beyond question a spinal implant manufacturer as defined in the Distribution Agreement, and NuVasive’s 2008 sales of Osteocel will violate Blackstone’s right to be the exclusive spinal implant manufacturer distributing Osteocel through at least the end of 2008, if not longer.

21. Second, upon closing of the APA, Osiris will enter into a Manufacturing Agreement under which NuVasive will be obliged to purchase at least 125,000 ccs of Osteocel between the closing date and April 15, 2009, and another 125,000 ccs between April 16, 2009 and eighteen months from the closing date. Given that Osiris’s total forecast production of Osteocel for the third and fourth quarters of 2008 totaled 120,000 ccs, 80% of which Blackstone

has committed to purchase, it is unlikely that Osiris can meet its production minimums under the APA while satisfying its product supply obligations to Blackstone.

22. Third, Blackstone has the right to renew the Distribution Agreement for successive one-year renewal terms beginning January 1, 2009, with the attendant right to remain the exclusive spinal implant manufacturer distributing Osteocel in the United States. Osiris has consistently stated in its public filings with the SEC that the Distribution Agreement “can be renewed for one-year periods so long as Blackstone achieves certain predetermined performance objectives.” Blackstone has satisfied all objective purchase requirements and other known performance objectives under the Agreement, and Osiris has never notified Blackstone of a shortcoming in its performance precluding renewal. Nevertheless, by letter dated July 7, 2008, Osiris already has informed Blackstone that any effort to renew the Agreement for 2009 and beyond will not be honored by Osiris or NuVasive. (And, indeed, it is difficult to understand why NuVasive would renew an agreement to allow an arch-competitor to continue selling a product for which NuVasive has offered to pay up to \$85,000,000.)

23. Fourth, Blackstone created a valuable and growing market for Trinity™-branded Osteocel through investments in equipment, training, product testing, and marketing, not to mention the good will created for Trinity™ by its association with Blackstone’s and Orthofix’s other highly respected products. In order to protect Blackstone’s investment in creating a market for Trinity™, Osiris and Blackstone agreed to the confidentiality provisions of the Distribution Agreement described above as well as to non-solicitation provisions prohibiting Osiris from soliciting agents or distributors of Blackstone during the term of the Distribution Agreement and for one year thereafter.

24. There is substantial risk that Osiris may turn over to NuVasive upon closing confidential information regarding the amount of Blackstone's sales of Trinity™, the identities of surgeons and hospitals purchasing Trinity™ from Blackstone, and the identities of Blackstone's network of sub-distributors selling Trinity™ and their respective sales. On July 9, 2008, for example, Michael Finegan, Orthofix's Vice President of Corporate Development, had a conversation with Jason Hannon, NuVasive's Senior Vice President and General Counsel, in which Mr. Hannon stated that he wanted the Distribution Agreement to be assigned to NuVasive under the APA so that NuVasive could glean information about the administration of the Distribution Agreement. Moreover, the APA specifically lists as an asset to be sold to NuVasive "all data and records related to the operation of the Osteocel business, including client and customer lists."

25. Blackstone has legitimate, good-faith claims to, (1) at a minimum, remain the exclusive spinal implant manufacturer for Osteocel in the United States through 2008; (2) renew the Distribution Agreement for successive one-year terms beginning January 1, 2009, during which terms Blackstone will retain its rights to purchase 80% of Osiris's production of Osteocel and be the exclusive U.S. spinal implant manufacturer distributing Osteocel; and (3) insure that none of its confidential information regarding Trinity™-branded Osteocel sales has been or will be disclosed to NuVasive as part of the proposed sale of Osteocel to NuVasive.

VI. Application for Injunctive Relief

26. Blackstone incorporates by reference and realleges all of the allegations in the preceding paragraphs.

27. Pursuant to the Court's authority to grant injunctive relief, Blackstone seeks the issuance of a temporary restraining order pending a preliminary injunction hearing and issuance

of a permanent injunction in aid of arbitration. Specifically, Blackstone requests that the Court issue a temporary restraining order and injunction preserving the status quo pending arbitration of Blackstone's claims in accordance with the Distribution Agreement's dispute resolution provisions and prohibiting Osiris from closing on its transaction to sell its Osteocel business to NuVasive until after the resolution of Blackstone's arbitrable claims.

28. Blackstone is entitled to injunctive relief because, if Osiris is permitted to close the transaction, Blackstone will be immediately and irreparably harmed because Blackstone's competitive position in the spinal products market will be irreversibly altered, and it will be impossible for an arbitrator to award relief sufficient or effective to put Blackstone in the position it would have enjoyed had Osiris honored Blackstone's rights of exclusivity, supply, and renewal under the Distribution Agreement. Blackstone's loss of profits and market share due to the unavailability of Trinity™ and NuVasive's introduction of its own branded version of Osteocel, and possible attendant erosion of sales of Blackstone's other spinal products, will be difficult if not impossible to accurately measure.

29. Blackstone is entitled to injunctive relief because there is a substantial likelihood of Blackstone's success on the merits. As mentioned above, the Distribution Agreement provides Blackstone with at least the following valuable rights:

- (a) the right to purchase 80% of Osiris's production of Osteocel packaged for resale as Trinity™;
- (b) the right to be the exclusive spinal implant manufacturer distributing Osteocel in the United States for the duration of the Distribution Agreement, provided Blackstone continues to commit to purchase 80% of Osiris's production of Osteocel; and

- (c) the right to renew the Distribution Agreement for successive one-year renewal terms following the expiration of the initial term on December 31, 2008.

While the Distribution Agreement is assignable under limited circumstances, it also provides: “Osiris agrees that it shall not enter into any agreement with or grant any rights to a Third Party that would conflict with or violate the terms of this Agreement.” If Osiris is permitted to close on its transaction to sell its Osteocel business to NuVasive, a competing spinal implant manufacturer, then it will breach at least these provisions of the Distribution Agreement.

30. Blackstone is entitled to injunctive relief because the risk of harm to Blackstone outweighs any harm that injunctive relief might inflict on Osiris. Blackstone will be irreparably harmed absent injunctive relief because Blackstone’s competitive position in the spinal products market may be irreversibly altered by Osiris’s sale of Osteocel to NuVasive, and it will be impossible for an arbitrator to award effective injunctive, declaratory, or monetary relief.

31. The issuance of a temporary restraining order poses no countervailing risk of harm to Osiris. Osiris and NuVasive agreed that the APA may be closed at any time up to and including September 8, 2008 without triggering default.

32. Blackstone is entitled to injunctive relief because the public interest will not be adversely affected by granting the requested injunctive relief. To the contrary, if injunctive relief is granted, the public interest in enforcing arbitration agreements will be served in that the status quo will have been preserved and the parties’ agreement to arbitrate will have actual meaning. Moreover, the injunctive relief sought by Blackstone will in no way limit the availability of Trinity™ to third parties such as surgeons and patients.

33. Blackstone is entitled to injunctive relief because Blackstone has no adequate remedy at law.

34. Blackstone is willing to post a bond, but requests that any bond imposed by the Court not exceed \$100,000 in light of the absence of harm to Osiris from the issuance of a temporary restraining order. Osiris and NuVasive agreed that the APA may be closed at any time up to and including September 8, 2008 without triggering default.

VII. Prayer

35. Wherefore, Blackstone respectfully requests that the Court issue a temporary restraining order and injunction preserving the status quo pending arbitration of Blackstone's claims in accordance with the Distribution Agreement's dispute resolution provisions and prohibiting Osiris from closing on its transaction to sell its Osteocel business to NuVasive until after the resolution of Blackstone's arbitrable claims. Blackstone further requests that it be awarded such other, alternative, or further relief, whether at law or in equity, to which it might be entitled.

Dated: July 23, 2008

Respectfully submitted,

By: 

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